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Signature	<i>Dave Glisson</i>	Date	August 24, 2000

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Atty Docket No.	CORA-011
First Named Inventor	Brent R. Constantz
Title:	FLUID DELIVERY SYSTEMS FOR DELIVERING FLUIDS TO MULTI-LUMEN CATHETERS

PTO
08/24/00
09/648282

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents

1. ☒ Fee Transmittal Form
2. ☒ Specification Total Pages 24
(preferred arrangement set forth below)
 - Descriptive title of the invention
 - Cross Reference to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to Microfiche Appendix

Address to: Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

5. ☐ Microfiche Computer Program (*Appendix*)
6. ☐ Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
 - a. ☐ Computer Readable Copy
 - b. ☐ Paper Copy (identical to computer copy)
 - c. ☐ Statement verifying identity of above copies

- Background of the Invention

ACCOMPANYING APPLICATION PARTS

- Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
3. ☒ Drawing(s) (35 USC 113) Total Sheets 5
 4. ☒ Oath or Declaration Total Sheets
 - a. ☒ Newly executed (original or copy)
 - b. ☐ Copy from a prior application (37 CFR 1.63(d)
(for continuation/divisional with Box 16 completed)
 - i. ☐ **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b)
 - c. ☐ Unsigned

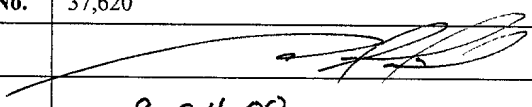
7. ☒ Assignment Papers (cover sheet & document(s))
8. ☐ 37 CFR 3.73(b) Statement ☒ Power of Attorney
(when there is an assignee)
9. ☐ English Translation Document (if applicable)
10. ☒ Information Disclosure Statement (IDS)/PTO-1449 ☒ Copies of IDS Citations
11. ☐ Preliminary Amendment
12. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
13. ☒ Small Entity Statement(s) ☐ Statement filed in prior application
Status still proper and desired
14. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
15. ☐ Other:

16. If a CONTINUING APPLICATION, check appropriate box and supply the requisite information:
☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No. _____

UTILITY PATENT APPLICATION TRANSMITTAL
(Only for new non-provisional applications under 37 CFR 1.53(b))

Atty Dkt No. *

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Signature	
Date	8.24.00

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**STATEMENT CLAIMING
SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27 (c))
SMALL BUSINESS CONCERN**

Attorney Docket	CORA-011
First Named Inventor	Brent R. Constantz
Application Number	N/A
Filing Date	Herewith
Title	Fluid Delivery Systems for....

I hereby state that I am:

- ☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf of the concern identified below;

NAME OF SMALL BUSINESS CONCERN: Corazón Technologies, Inc
 ADDRESS OF SMALL BUSINESS CONCERN: 199 Jefferson, Menlo Park CA 94025

I hereby state that the above-identified small business concern qualifies as a small business concern as defined in 37 CFR 121 for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention described in:

Fluid Delivery Systems for Delivering Fluids to Multi-Lumen Catheters

- ☒ the specification filed herewith with title as listed above.
☐ the application identified above.
☐ the patent identified above.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention must file separate statements as to their status as small entities, and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or by a nonprofit organization under 37 CFR 1.9(e).

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- ☒ no such person, concern, or organization exists.
☐ each such person, concern, or organization is listed below.

NAME: _____

ADDRESS: _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

Separate statements are required from each named person, concern or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

SIGNATURE Brent Constantz DATE: 8-22-00
 NAME OF PERSON SIGNING: Brent R. Constantz
 TITLE IN ORGANIZATION OF PERSON SIGNING: President
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Atty Docket No. CORA-011

Date of Deposit August 21, 2000

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Dave Glisson

Typed or Printed Name of Person Mailing Paper or Fee

Dave Glisson

Signature of Person Mailing Paper or Fee

PATENT APPLICATION

FLUID DELIVERY SYSTEMS FOR DELIVERING FLUIDS TO
MULTI-LUMEN CATHETERS

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FLUID DELIVERY SYSTEMS FOR DELIVERING FLUIDS TO MULTI-LUMEN CATHETERS

INTRODUCTION

Field of the Invention

15 The field of this invention is atherosclerosis and related vascular conditions, and particularly catheter devices used for treating such conditions.

Background of the Invention

20 The formation of plaques or lesions, (atherosclerotic plaques or lesions) on vascular tissue, such as the inner surface of blood vessels, aortic valves, etc., is a major component of various vascular disease conditions. For example, plaques on heart related vascular structures, e.g., coronary artery intima, heart valves, etc., are often implicated in various heart disease conditions. Likewise, plaques or lesions present on the intima of peripheral vessels, e.g., arteries, are often implicated in various peripheral vascular disease conditions.

25 A variety of different protocols have been developed for treating diseases associated with the presence of vascular lesions or plaques. Such treatment methodologies generally involve mechanical removal or reduction of the lesion, and include: bypass surgery, balloon angioplasty, mechanical debridement, atherectomy, valve replacement, and the like. Despite the plethora of different treatment strategies that have
30 been developed for the treatment of such vascular disease conditions, there are disadvantages associated with each technique, such as tissue damage, invasiveness, etc. For example, restenosis is a common complication that results in arteries in which lesions have been mechanically removed.

5 As such, there is continued interest in the development of new treatment protocols for the removal of vascular lesions from vascular tissue, as well as catheter devices that are used in such protocols.

Relevant Literature

U.S. Patents of interest include: 6,063,052; 6,048,334; 6,042,565; 5,997,502;
10 5,947,935; 5,944,694; 5,916,197; 5,827,219; 5,795,333; 5,741,232; 5,520,653; 5,383,858; 4,854,324; 4,677,980; and 4,370,982. Also of interest are U.S. Patent Nos. 4,329,994; 4,838,881; 5,149,330; 5,167,623; 5,207,648; 5, 542,937; 6,004,310; and 6,013,068. Also of interest are U.S. Patent Nos.: 4,445,892; 4,573,966; 4,610,662; 4,636,195; 4,655,746; 4,824,436; 4,911,163; 4,976,733; 5,059,178; 5,090,960; 5,167,628; 5,195,955; 5,222,941;
15 5,380,284; 5,443,446; and 5,462,529. See also: WO 00/03651, the disclosure of which is herein incorporated by reference.

SUMMARY OF THE INVENTION

Fluid delivery systems capable of introducing first and second fluids into first and
20 second lumens of a multi-lumen catheter at predetermined flow rates, and often substantially the same flow rates are provided. The first and second fluids are generally a dissolution fluid and a dissolution fluid attenuating fluid. Also provided are fluid delivery devices and kits that include the subject systems. The subject fluid delivery systems find use in a variety of different applications, and are particularly suited for use in the chemical
25 ablation of internal vascular lesions.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 provides a representation of a fluid delivery system according to a first embodiment of the subject invention.

30 Figures 2A to 2C provide a representation of a second embodiment of the subject fluid delivery system.

Figure 3 provides a depiction of yet another embodiment of the subject fluid delivery system.

Figure 4 provides a representation of yet another embodiment of the subject fluid
35 delivery system.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Fluid delivery systems capable of introducing first and second fluids into first and second lumens of a multi-lumen catheter at a predetermined, and often at substantially the same, flow rate are provided. The first and second fluids are generally a dissolution fluid and a dissolution fluid attenuating fluid. Also provided are fluid delivery devices and kits that include the subject systems. The subject fluid delivery systems, devices and kits find use in a variety of different applications, and are particularly suited for use in the chemical ablation of internal vascular lesions, particularly where a vascular site is flushed with a dissolution fluid and a dissolution fluid attenuating fluid. In further describing the subject invention, the subject fluid delivery systems will be described first, both generally and in terms of the figures, followed by a description of : (a) representative methods in which the subject systems find use; and (b) and the subject kits.

Before the subject invention is described further, it is to be understood that the invention is not limited to the particular embodiments of the invention described below, as variations of the particular embodiments may be made and still fall within the scope of the appended claims. It is also to be understood that the terminology employed is for the purpose of describing particular embodiments, and is not intended to be limiting. Instead, the scope of the present invention will be established by the appended claims.

It must be noted that as used in this specification and the appended claims, the singular forms "a," "an," and "the" include plural reference unless the context clearly dictates otherwise. Unless defined otherwise all technical and scientific terms used herein have the same meaning as commonly understood to one of ordinary skill in the art to which this invention belongs.

30

FLUID DELIVERY SYSTEMS

As summarized above, the present invention provides systems for delivering at least two different fluids into separate lumens of a multi-lumen catheter, where the fluids are introduced into the two different lumens of the multi-lumen catheter at a predetermined or set flow rate. By predetermined or set flow rate is meant that the flow

5 rate is known and controlled in a known manner, e.g., as is accomplished using a metered or automated fluid delivery means, such as described in U.S. Patent No. 6,063,052, the disclosure of which is herein incorporated by reference.

In many embodiments, the first and second fluids are delivered by the subject fluid delivery systems to the first and second lumens, respectively, at substantially the same flow rate. In other words, in many embodiments the subject systems are capable of delivering a first fluid into one lumen of a multi-lumen catheter at a flow rate that is substantially the same as, if not identical to, the flow rate of a second fluid that is introduced by the system into a second lumen of the same multi-lumen catheter. By "substantially the same as" is meant that any variation in flow rates, if present at all, between the first and second introduced fluids does not exceed about 10 cc/min, and usually does not exceed about 2 cc/min in magnitude.

A feature of the subject systems is that they include a means for delivering at least two different fluids, i.e., a fluid dispensing means, into separate lumens of a multi-lumen catheter, where, in many embodiments, each of the different fluids introduced by the subject means is delivered into its respective lumen of the multi-lumen catheter at substantially the same, if not the same, flow rate. Generally, the subject fluid dispensing means is a means for moving first and second fluids out of first and second fluid reservoirs and into first and second lumens of a multi-lumen catheter, where the fluid reservoirs are generally in fluid communication with their respective lumens of the multi-lumen catheter by tubing or analogous fluid conveyance means, where the connections between the reservoir, tubing and lumens may include valves, stop-cocks etc., as desirable, where a multitude of different connection means are known to those of skill in the art.

The subject fluid dispensing means may be made up of a single, integral structure or two or more disparate and readily separable elements, but typically includes the following components: two distinct fluid reservoirs and a means for increasing the internal pressure in each distinct fluid reservoir, i.e., a pressurization means. The first and second fluid reservoirs have a volume sufficient to hold an amount of fluid that is requisite for the intended use, where the volume of each reservoir is generally at least about 50, usually at least about 100 and more usually at least about 120 ml, where the

5 volume may be as great as about 400 ml or greater, but generally does not exceed about 150 ml and usually does not exceed about 120 ml. Each fluid reservoir is further characterized by generally having a single fluid port by which fluid leaves the reservoir upon increase of internal pressure inside the fluid reservoir. The single fluid port or opening generally includes a removable sealing means, e.g., a valve or analogous
10 structure, that can be opened to provide for fluid flow through the port. The diameter of the port is large enough to provide for the desired fluid flow rate out of the reservoir, and typically ranges from about 1 to 5 mm, usually from about 1 to 2 mm.

As mentioned above, the subject fluid dispensing means include two different fluid reservoirs, i.e., a first and second fluid reservoir. The first fluid reservoir houses or
15 stores a quantity of a dissolution fluid, while the second fluid reservoir houses or stores a quantity of a dissolution fluid attenuating fluid. Where the target lesion is made up of organic matter, of interest as dissolution fluids and dissolution fluid attenuating fluids are surfactant/detergent solutions and dilution solutions (e.g., saline, water), such as those described in U.S. Patent Application No. 09/528,576; the disclosure of which is herein
20 incorporated by reference. In other embodiments where the target lesion comprises inorganic matter, acidic dissolution solutions and their companion pH elevating, e.g., buffer, attenuating fluids are of interest, such as those described in WO 00/03651; the disclosure of which is herein incorporated by reference.

The first and second fluid reservoirs are designed such that the internal pressure of
25 the reservoirs can be increased to provide for fluid flow at a desired or set flow rate, i.e., a predetermined metered flow rate, out of the reservoir through the fluid port. The internal pressure of the reservoir may, in general, be increased using any convenient protocol, e.g., by introduction of a gas into the reservoir. As such, in many embodiments, the fluid reservoirs are compressible, by which is meant that one or more walls of the reservoirs
30 may be moved relative to the others in a manner that provides for a decrease in the volume of the reservoir (and concomitant expulsion of fluid out the port), where the one or more walls of the reservoir is movable upon application of a sufficient force to the wall. Generally, the amount of force required to move the wall of the reservoir ranges from about 50 to 1000 lb, usually from about 200 to 800 lb and more usually from about 500 to
35 600 lb. Where the fluid reservoirs are compressible, they should be capable of going from

5 a first volume to a second volume, where the second volume is typically less than 10%, usually less than 5% and more usually less than 1 % of the first volume.

The first and second fluid reservoirs may be present in a single, integral component of the fluid delivery means or present as two disparate components, depending on the nature of the fluid delivery means. Representative configurations of the first and
10 second fluid reservoirs relative to each other are reviewed below.

The other essential component of the fluid dispensing means is a means for increasing the internal pressure of each fluid reservoir to provide for fluid exit from the reservoir in a controlled or metered manner. This pressurization means may take a variety of different configurations, depending on the particular fluid dispensing means in which it
15 is located. As discussed above, the fluid reservoirs in many embodiments of the subject invention are ones that are compressible. As such, in many embodiments of the invention, the pressurization means is a means for compressing one or more walls of the fluid reservoir in a manner sufficient to provide for the desired increase in pressure and the concomitant metered flow of fluid out of the reservoir through the port. In these
20 embodiments, the means for the compressing one or more walls of the reservoir, i.e., the compression means, is typically a flat or planar element and a means for pushing the flat or planar element against one side of the reservoir with a force sufficient to compress the reservoir, where the force typically ranges from about 50 to 1000, usually from about 200 to 800 and more usually from about 500 to 600 lb, as described above.

As with the fluid reservoirs, this pressurization means may be present in a variety of different configurations depending on the particular nature of the fluid delivery means, e.g., whether it is a single integral component or made up of disparate components, which disparate components may or may not be physically together during use. As such, in certain embodiments the pressurization means is made up of two distinct and separately
25 controllable or actuatable compression means, while in other embodiments the pressurization means is made up of a single actuatable compression means which is capable of simultaneously compressing both reservoirs.
30

As mentioned above, the fluid delivery means may be made up of a single, integral structure or two more disparate structures, which disparate structures may or may not be
35 physically together during use. An example of a fluid delivery means made up of two

5 physically distinct disparate structures is two separately actuatable metered fluid delivery devices, e.g., two separate metered fluid dispensing devices, e.g., as described in U.S. Patent Nos. 6,063,052; 6,048,334; 6,042,565; 5,997,502; 5,947,935; 5,944,694; 5,916,197; 5,827,219; 5,795,333; 5,741,232; 5,520,653; 5,383,858; 4,854,324; 4,677,980; and 4,370,98; the disclosures of which are herein incorporated by reference, where each
10 device has one of the two fluid reservoirs and thereby houses one of the two fluids, e.g., the dissolution fluid and the dissolution fluid attenuating fluid. In other embodiments of the fluid delivery means, the first and second fluid reservoir are present in the same structure, which structure also includes a pressurization means that is capable of compressing the first and second fluid reservoirs, as described above. The fluid reservoirs
15 of this embodiment of the fluid delivery means may or may not be capable of being readily removed from the remainder of the structure, e.g., where the fluid reservoirs are present in a cartridge, as described in greater detail below. The pressurization means may be made up of two separately actuatable compression means or a single compression means that includes two different planar elements, e.g., an element for reach fluid
20 reservoir.

The subject fluid delivery systems are designed for delivering a dissolution fluid and a dissolution fluid attenuating fluid into two separate lumens of a multi-lumen catheter or multi-lumen catheter system, where each fluid is delivered at a desired flow rate. Generally, the flow rate of each fluid is at least about 05 cc/sec, usually at least about
25 1 cc/sec and more usually at least about 2 cc/sec, where the flow rate may be as great as 5 cc/sec or greater, but generally does not exceed about 1 cc/sec and usually does not exceed about 2 cc/sec. As mentioned above, in many embodiments, the subject systems are capable of delivering the two different fluids to their respective lumens at substantially the same flow rate. In other embodiments, the subject systems are capable of delivering
30 two different fluids at rates that are not substantially the same, but are fixed relative to each other, e.g., a fixed ratio, such that the two different fluids may be delivered at different rates that are nonetheless substantially constant and are therefore delivered at a fixed ratio of rates.

The subject fluid delivery systems may be employed with a variety of different
35 multi-lumen catheters. Representative multi-lumen catheter devices that may be adapted

5 for use in the subject methods include those described in U.S. Patent Nos.: 329,994;
4,838,881; 5,149,330; 5,167,623; 5,207,648; 5,542,937; and 6,013,068; the disclosures of
which are herein incorporated by reference. The subject fluid delivery systems are
particularly suited for use in delivering fluid to the multi-lumen catheters described in
U.S. Patent Application Serial Nos. 09/_____ (Atty Docket No. CORA-010);
10 09/425,826; 09/384,860; and 09/528,576; as well as PCT Publication No. WO 00/03651;
the disclosures of which are herein incorporated by reference.

Representative fluid delivery systems according to the subject invention are
described in greater detail in terms of the figures. Figure 1 provides a representation of a
fluid delivery system according to a first embodiment of the subject invention. In Figure
15 1, fluid delivery system 10 is shown connected in fluid communication with multi-lumen
catheter system 11 as would be found during use of the subject delivery system. Fluid
delivery system 10 is made up of two separate metered fluid delivery means or dispensing
means 12 and 14, as described above, which devices are capable of providing for a
controlled, metered flow of fluid, e.g., dissolution fluid or dissolution fluid attenuating
20 fluid housed in the reservoirs present therein. Dispensing means 12 includes first fluid
reservoir filled with dissolution fluid and dispensing means 14 includes the second fluid
reservoir filled with dissolution fluid attenuating fluid. Multi-lumen catheter system 11
includes aspiration catheter 17 and total occlusion catheter 19. Also shown are balloon
inflation line 15, balloon inflation syringe 13, aspiration line 18 and negative pressure
25 source 16.

Figures 2A to 2C provide a representation of a second embodiment of the subject
fluid delivery systems. In Figure 2A, fluid delivery system 20 is shown operationally
connected to multi-lumen catheter system 21. Fluid delivery system 20 is a single integral
structure which is pneumatically or analogous powered and includes cartridge 22 that
30 includes the first and second fluid reservoirs filled, respectively, with dissolution fluid and
dissolution fluid attenuating fluid. The multi-lumen catheter system 21 includes aspiration
catheter 23 and total occlusion catheter 25, where the system is shown attached to balloon
inflation syringe 27b via balloon inflation line 27a and negative pressure source 29a via
aspiration line 29b. Figure 2B provides a cutaway view of the fluid dispensing means 20
35 shown in Figure 2A. As shown in Figure 2B, present in fluid dispensing means 20 are first

5 and second fluid reservoirs 24 and 26, as well as compressing means 28. Compressing means 28 is a unified system that is capable of compressing both first and second fluid reservoirs simultaneously. Figure 2C provides a representation of the disposable cartridge 22 that fits into the pressurization means, made up of the compressing means 28 and the actuation means thereof, e.g., the pneumatic actuation means, to produce the fluid delivery
10 means 20. The disposable cartridge 22 includes filled fluid reservoirs 24 and 26, which fluid reservoirs each have a single opening 24a and 26a which allows fluid to flow out of the reservoirs upon compression of the reservoirs by the compression means. The fluid openings 24a and 26a are standard luer connectors.

Figure 3 provides a depiction of yet another embodiment of the subject fluid
15 delivery system. In Figure 3, fluid delivery system 30 includes disposable cartridge 32 which houses the first and second fluid reservoirs (not shown). The first and second fluid reservoirs are operationally connected with multi-lumen catheter system 31, which system is made up of aspiration catheter 33 and total occlusion catheter 35. Also shown is balloon inflation syringe 39a connected to aspiration catheter 33 via balloon inflation line 39b.
20 The fluid delivery system is actuated by a compressed air source (not shown) to which the delivery system 30 is connected via compressed air line 34. The delivery system is controlled via foot switch 36. Also shown is disposable vacuum bottle 37a which is connected to the multi-lumen catheter system via aspiration line 37b and serves as the negative pressure source. Aspiration can be triggered via foot switch 36. Fluid delivery
25 means 30 includes a holder for the vacuum bottle 37a.

Figure 4 provides a representation of yet another embodiment of the subject fluid delivery system. In Figure 4, fluid delivery system 40 is made up of a housing 42 which houses the first and second reservoirs which may be viewed through windows 44a and 44b. Housing also includes compression means, not shown, which is actuated by
30 compressed gas cartridge 46. As such, housing 42 includes a cartridge receiving area or holder. Also present on housing 42 is a vacuum bottle holder for holding a vacuum bottle 47a which serves as the negative pressure means of the system. The fluid delivery means is designed to be hung on a hook via hole 48. Also shown in Figure 4 is multi-lumen catheter system 41, which is made up of aspiration catheter 43 and total occlusion catheter
35 45. Also shown is balloon inflation syringe 49. During use, dissolution fluid tubing 51 and

5 attenuating fluid tubing 53 establish fluid communication between the first and second
reservoirs of the fluid delivery device and the total occlusion catheter of the multi-lumen
catheter system. In addition, vacuum bottle 47a is connected to the aspiration catheter 43
via aspiration line 47b.

10 METHODS

The subject fluid delivery systems find use in applications where it is desired to
flush a vascular target site with two different fluids, particularly at the same time or
simultaneously. As mentioned above, by flush is meant that the fluid is introduced into the
15 vascular site and removed from the vascular site in manner such that the vascular site
remains substantially isobaric, i.e., the pressure in the vascular site remains substantially
constant. While the subject systems can, in principle, be employed to flush a vascular site
with any two fluids, they are particularly suited for use in applications where chemical
tissue ablation at a target vascular site is desired. As such, the subject systems find
20 particular use in the treatment of vascular lesions or obstructions, where the target lesions
or obstructions may be organic, inorganic or composite structures of both organic and
inorganic components. In such embodiments, the systems are used to flush the target
vascular site, and therefore the lesion or obstruction located therein, with a dissolution
fluid and a dissolution fluid attenuating fluid.

25 In these embodiments of the subject methods, the first step is generally to provide
for an entry site for the multi-lumen catheter into the vascular system of the host. Entry is
typically provided by placement of an introducer sheath at a convenient location, e.g., leg
etc., as is known in the art. A guidewire is then inserted through the entry sheath and its
distal end is placed at the target vascular site. Next, the multi-lumen catheter system is
30 positioned inside the vascular system, where the particular protocol for this positioning
step generally depends on the nature of the particular multi-lumen catheter being
employed.

Following positioning of the multi-lumen catheter, fluid communication is
established between a first lumen of the catheter and the first fluid reservoir and a second
35 lumen of the catheter and the second fluid reservoir. Fluid communication is typically

5 established by connecting the first lumen to the port of the first reservoir and the second lumen to the port of the second reservoir, typically via a connecting tube or analogous fluid conveyance means.

Following establishment of fluid communication, as described above, the fluid delivery means is actuated in a manner to provide for fluid flow from the first and second
10 reservoirs into the first and second lumens, respectively, of the multi-lumen catheter. The flow rate of fluid into the first and second lumens typically ranges from about 0.5 to 5 cc/sec, usually from about 0.5 to 3.0 cc/sec and more usually from about 1 to 2 cc/sec.

In this manner the dissolution fluid and dissolution fluid attenuating fluid are introduced into the vascular site via the appropriate lumens inside the multi-lumen
15 catheter. In addition, fluid is removed from the vascular site via another lumen of the multi-lumen catheter, e.g., the aspiration lumen of the multi-lumen. The target vascular site is flushed with the dissolution and dissolution fluid attenuating fluids for a period of time sufficient to result in the desired amount of treatment, e.g., target lesion size reduction, enhancement or establishment of fluid flow through the target site, etc.
20 Following the desired amount of treatment, the system is removed from the host. More specific detail regarding the methods in which the subject systems find use can be found in U.S. Patent No. 09/528,576 and publication no. WO 00/03651; the disclosures of which are herein incorporated by reference.

In certain embodiments, the methods are further characterized by the application
25 of mechanical energy to the target lesion, e.g., to disrupt or dislodge at least a portion of the target lesion and thereby promote dissolution thereof by the dissolution fluid, e.g., by increasing the surface area of the lesion that is accessible by the dissolution fluid.

Mechanical means of interest include moving structures, e.g. rotating wires, guidewires, which physically contact the target occlusion and thereby apply physical mechanical
30 energy to the target lesion. Specific means of interest include: (a) guidewires that disrupt, dislodge, agitate or otherwise mechanically disrupt the target lesion; (b) angioplasty devices, e.g., high pressure balloons that can compress plaque against the vessel wall; (c) atherectomy devices, e.g., devices with rotating burrs that break up plaque into small pieces or can cut/excise the plaque, e.g., the Scimed Rotoblator™, Guidants'

- 5 Atherocath®, etc.; (d) laser ablation devices, such as those being developed by Spectranetics; and the like.

KITS

- 10 Also provided by the subject invention are kits for use in flushing a vascular site with two fluids. The subject kits at least include first and second reservoirs, as described above, suitable for use in the subject fluid delivery systems. The first and second fluid reservoirs are generally present in the form of a cartridge or cartridges, depending on whether the fluid delivery system is a single structural unit or made up of disparate
15 structural units, e.g., two separate metered fluid dispensing devices. The cartridge or cartridges will be filled with dissolution fluid or dissolution fluid attenuating fluid.

- In addition to the filled fluid reservoirs as described above, the subject kits typically further include one or more additional components of the subject fluid delivery systems and/or components that find use in flushing a vascular site with the two fluids.
20 Additional components of the fluid delivery system that may be present include, but are not limited to: tubing or analogous fluid conveyance means for establishing fluid communication between the reservoirs and the lumens of a multi-lumen catheter; a power source for the pressurization means of the delivery system, e.g., pressurized gas source, such as CO₂ cartridge; a negative pressure means, e.g., a vacuum bottle; a holder for the
25 various components of the system; and the like.

- The kits of the subject invention may also include a number of different components that find use in flushing a vascular site with the fluids of the fluid delivery systems. In many embodiments, the kits will include a multi-lumen catheter or catheter system, as described above. In certain embodiments, the kits further include a guidewire.
30 Any convenient type of guidewire may be present, where a number of different guidewires are known to those of skill in the art. Guidewires of interest include those described in U.S. Patent Nos. 6,007,514; 5,980,471; 5,957,865; 5,938,609; 5,931,819; 5,916,178; 5,908,395; 5,902,254; 5,865,767; 5,827,201; 5,788,654; 5,772,609; 5,769,796; 5,755,695; 5,749,837; 5,682,897; 5,660,180; 5,636,642; 5,606,981; 5,599,492; 5,596,996;
35 5,558,093; 5,546,948; 5,520,189; 5,507,301; 5,497,782; D363,776; 5,460,187; 5,441,497;

5 5,437,288; 5,427,118; 5,421,349; 5,411,033; 5,409,015; 5,368,035; 5,341,818; 5,339,833;
5,313,967; 5,303,714; RE34,466; 5,265,622; 5,238,005; 5,184,621; 5,167,239; 5,147,317;
5,144,959; 5,111,829; 5,107,852; 5,095,915; 5,095,911 5,084,022; 5,069,226; 5,063,935;
4,966,163; 4,953,553; 4,875,489; 4,827,941; 4,811,743; 4,676,249; 4,534,363; 4,080,706;
4,003,369; the disclosures of which are herein incorporated by reference. Also of interest
10 are dilators for use in creating entries into the vascular system of the host.

Additional optional components that may be present in kits of the subject invention include various fluids and solutions in addition to the dissolution fluid and dissolution fluid attenuating fluid described above. Additional fluids that may be present include: organic matter dissolution fluids, wash or rinsing fluids, imaging agent fluid
15 mediums that include an imaging agent, such as a non-ionic imaging agents, e.g., CONRAY™, OXILAN™, fluids containing one or more pharmacological agents, e.g., agents that promote healing, reduce inflammation, and the like; etc.

Other components that may be present in the subject kits include one or more additional components and accessories for use with the fluid delivery means present in the
20 kit, including tubing for connecting the various catheter components with fluid reservoirs, syringes, pumping means, etc., connectors, stop-cocks, dilators, insertion sheaths, vacuum regulators, negative pressure means, luer valve adapters, etc.

In addition to above mentioned components, the subject kits typically further include instructions for using the components of the kit to flush a vascular site with two
25 different fluids, e.g., to flush a vascular site with a dissolution fluid and a dissolution fluid attenuating fluid. The instructions for practicing the subject methods are generally recorded on a suitable recording medium. For example, the instructions may be printed on a substrate, such as paper or plastic, etc. As such, the instructions may be present in the kits as a package insert, in the labeling of the container of the kit or components thereof
30 (i.e., associated with the packaging or subpackaging) etc. In other embodiments, the instructions are present as an electronic storage data file present on a suitable computer readable storage medium, e.g. CD-ROM, diskette, etc. In yet other embodiments, the actual instructions are not present in the kit, but means for obtaining the instructions from a remote source, e.g. via the internet, are provided. An example of this embodiment is a
35 kit that includes a web address where the instructions can be viewed and/or from which

5 WHAT IS CLAIMED IS:

1. A fluid delivery system for delivering at least two different fluids into separate lumens of a multi-lumen catheter, said system comprising:
a first fluid reservoir comprising a dissolution fluid; and
10 a second fluid reservoir comprising a dissolution fluid attenuating fluid.
2. The system according to Claim 1, wherein said system comprises a separate fluid dispensing means for each of said dissolution fluid and dissolution fluid attenuating fluid.
- 15 3. The system according to Claim 2, wherein each of said fluid dispensing means is a metered fluid dispensing means.
4. The system according to Claim 1, wherein said system comprises a single fluid dispensing means for each of said at least two different fluids.
- 20 5. The system according to Claim 4, wherein said single fluid dispensing means is a metered fluid dispensing means.
6. A system for flushing an internal site with two different fluids, said system
25 comprising:
 (a) a multi-lumen catheter;
 (b) a fluid delivery system according to Claim 1; and
 (c) a negative pressure means sufficient to aspirate fluid from a lumen of said multi-lumen catheter.
- 30 7. The system according to Claim 6, wherein said fluid delivery system comprises a separate first and second fluid dispensing means.
8. The system according to Claim 7, wherein said first and second fluid dispensing
35 means are metered fluid dispensing means.

9. The system according to Claim 6, wherein said fluid delivery system comprises a single fluid dispensing means comprising first and second fluid reservoirs.

10. The system according to Claim 9, wherein said single fluid dispensing means is a metered fluid dispensing means.

11. The system according to Claim 10, wherein said metered dispensing means comprises a cartridge that includes first and second fluid reservoirs.

12. The system according to Claim 11, wherein said metered dispensing means comprises a means for increasing the internal pressure of each of said first and second fluid reservoirs.

13. The system according to Claim 12, wherein said means for increasing the internal pressure of each of said first and second fluid reservoirs comprises a separate compression means for each of said first and second fluid reservoirs.

14. The system according to Claim 12, wherein said means for increasing the internal pressure of each of said first and second fluid reservoirs comprises a single compression means for each of said first and second fluid reservoirs.

15. The system according to Claim 6, wherein said system further comprises a balloon inflation means.

16. A system for simultaneously flushing an internal site with two different fluids, said system comprising:

(a) a multi-lumen catheter comprising first, second and third lumens;

(b) a metered fluid delivery system comprising a first reservoir containing a dissolution fluid and a second reservoir containing a dissolution fluid attenuating fluid,

wherein said metered fluid delivery means is capable of delivering said first and second

- 5 fluids into said first and second lumens of said multi-lumen catheter at substantially the same flow rate;
- (c) a negative pressure means sufficient to aspirate fluid from said third lumen of said multi-lumen catheter;
- (d) a balloon inflation means.

10

17. The system according to Claim 16, wherein said metered fluid delivery system comprises a means for increasing the internal pressure of each of said first and second fluid reservoirs.

- 15 18. The system according to Claim 17, wherein said means for increasing the internal pressure of each of said first and second fluid reservoirs comprises a separate compression means for each of said first and second fluid reservoirs.

19. The system according to Claim 17, wherein said means for increasing the internal
20 pressure of each of said first and second fluid reservoirs comprises a single compression means for each of said first and second fluid reservoirs.

20. The system according to Claim 17, wherein said first and second fluid reservoirs are present in a cartridge.

25

21. A fluid storage means, wherein said fluid storage means comprises:
at least two fluid reservoirs, wherein a first of said at least two fluid reservoirs contains a dissolution fluid and a second of said at least two fluid reservoirs contains a dissolution fluid attenuating fluid.

30

22. The fluid storage means according to Claim 21, wherein said fluid storage means has only a first and second fluid reservoir.

5 23. The fluid storage means according to Claim 21, wherein said dissolution fluid is selected from the group consisting of: an organic matter dissolution fluid and an inorganic matter dissolution fluid.

24. The fluid storage means according to Claim 23, wherein said inorganic matter
10 dissolution fluid is an acidic dissolution fluid.

25. The fluid storage means according to Claim 23, wherein said organic matter dissolution fluid comprises a detergent.

15 26. The fluid storage means according to Claim 24, wherein said dissolution fluid attenuating fluid is a pH elevating solution.

27. The fluid storage means according to Claim 26, wherein said pH elevating
20 solution is a buffer solution.

28. The fluid storage means according to Claim 21, wherein each of said two fluid reservoirs comprises an outlet port.

29. The fluid storage means according to Claim 21, wherein each of said two fluid
25 reservoirs is compressible.

30. The fluid storage means according to Claim 21, wherein said fluid storage means is a cartridge.

30 31. A cartridge containing:
a first compressible fluid reservoir having an outlet port and comprising a dissolution fluid; and
a second compressible fluid reservoir having an outlet port and comprising a dissolution fluid attenuating fluid.

35

- 5 32. The cartridge according to Claim 31, wherein said dissolution fluid is selected from the group consisting of an inorganic matter dissolution fluid and an organic matter dissolution fluid.
33. The cartridge according to Claim 32, wherein said inorganic matter dissolution
10 fluid is an acidic solution.
34. The cartridge according to Claim 32, wherein said organic matter dissolution fluid comprises a detergent.
- 15 35. The cartridge according to Claim 31, wherein said dissolution fluid attenuating fluid is a pH elevating fluid.
36. The cartridge according to claim 35, wherein said pH elevating fluid is a buffer
20 solution.
37. A fluid delivery system comprising:
- (a) a cartridge containing:
 - (i) a first compressible fluid reservoir having an outlet port and comprising a dissolution fluid; and
 - 25 (ii) a second compressible fluid reservoir having an outlet port and comprising a dissolution fluid attenuating fluid;
 - (b) a housing comprising a holder for said cartridge.
38. The fluid delivery device according to Claim 37, wherein said device further
30 comprises a means for compressing said compressible fluid reservoirs.
39. The fluid delivery device according to Claim 37, wherein said means for compressing said compressible fluid reservoirs comprises a pressurized gas source.

5 40. The fluid delivery device according to Claim 39, wherein said pressurized gas source is present in a pressurized gas source holder in said housing.

41. The fluid delivery device according to Claim 37, wherein said device comprises a vacuum bottle holder.

10

42. A method for delivering at least two fluids into two separate lumens of a multi-lumen catheter, said method comprising:

- (a) establishing fluid communication between said two separate lumens and a fluid delivery system according to Claim 1; and
- 15 (b) actuating said fluid delivery system in a manner sufficient to deliver said at least two different fluids into different lumens of said multi-lumen catheter;

whereby said at least two fluids are delivered into different lumens at substantially the same rate.

20

43. The method according to Claim 42, wherein said fluid delivery means comprises at least two separate fluid reservoirs and said actuating comprises increasing the pressure inside said at least two separate fluid reservoirs.

25 44. The method according to Claim 43, wherein said pressure inside said at least two separate fluid reservoirs is increased by compressing said at least two separate fluid reservoirs.

30 45. A method for simultaneously flushing an internal vascular site of a host with two different fluids, said method comprising:

- (a) providing a system comprising:
 - (i) a multi-lumen catheter comprising first, second and third lumens;
 - (ii) a metered fluid delivery system comprising a first reservoir containing a dissolution fluid and a second reservoir containing a
- 35 dissolution fluid attenuating fluid, wherein said metered fluid

5 delivery means is capable of delivering said fluids into said first and second lumens of said multi-lumen catheter at substantially the same flow rate; and

(iii) a negative pressure means sufficient to aspirate fluid from said third lumen of said multi-lumen catheter;

10 (b) positioning a distal end of said multi-lumen catheter at said internal vascular site;

(c) actuating said metered fluid delivery means and said negative pressure means in a manner sufficient to introduce and remove fluid from said vascular site and maintain substantially isobaric conditions at said vascular site;

15 whereby said internal vascular site is simultaneously flushed with said fluids.

46. A kit for use in flushing an internal vascular site with two different fluids, said kit comprising:

20 (a) a fluid storage means comprising first and second fluid reservoirs, wherein a first fluid reservoir contains a dissolution fluid and said second fluid reservoir contains a dissolution fluid attenuating fluid; and

(b) instructions for using said fluid storage means in a system according to Claim 1.

25 47. The kit according to Claim 46, wherein said kit further comprises a means for moving said dissolution fluid and said dissolution attenuating fluid from said first and second fluids reservoirs into first and second lumens of a multi-lumen catheter at substantially the same rate.

30 48. The kit according to Claim 46, wherein said fluid storage means is in the form a cartridge.

49. The kit according to Claim 48, wherein said kit comprises a fluid delivery device
35 according to Claim 37.

[illegible]

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5 FLUID DELIVERY SYSTEMS FOR DELIVERING FLUIDS TO MULTI-LUMEN CATHETERS

ABSTRACT OF THE DISCLOSURE

Fluid delivery systems capable of introducing first and second fluids into first and second lumens of a multi-lumen catheter are provided. The first and second fluids are generally a dissolution fluid and a dissolution fluid attenuating fluid. Also provided are fluid delivery devices and kits that include the subject systems. The subject fluid delivery systems find use in a variety of different applications, and are particularly suited for use in the chemical ablation of internal vascular lesions.

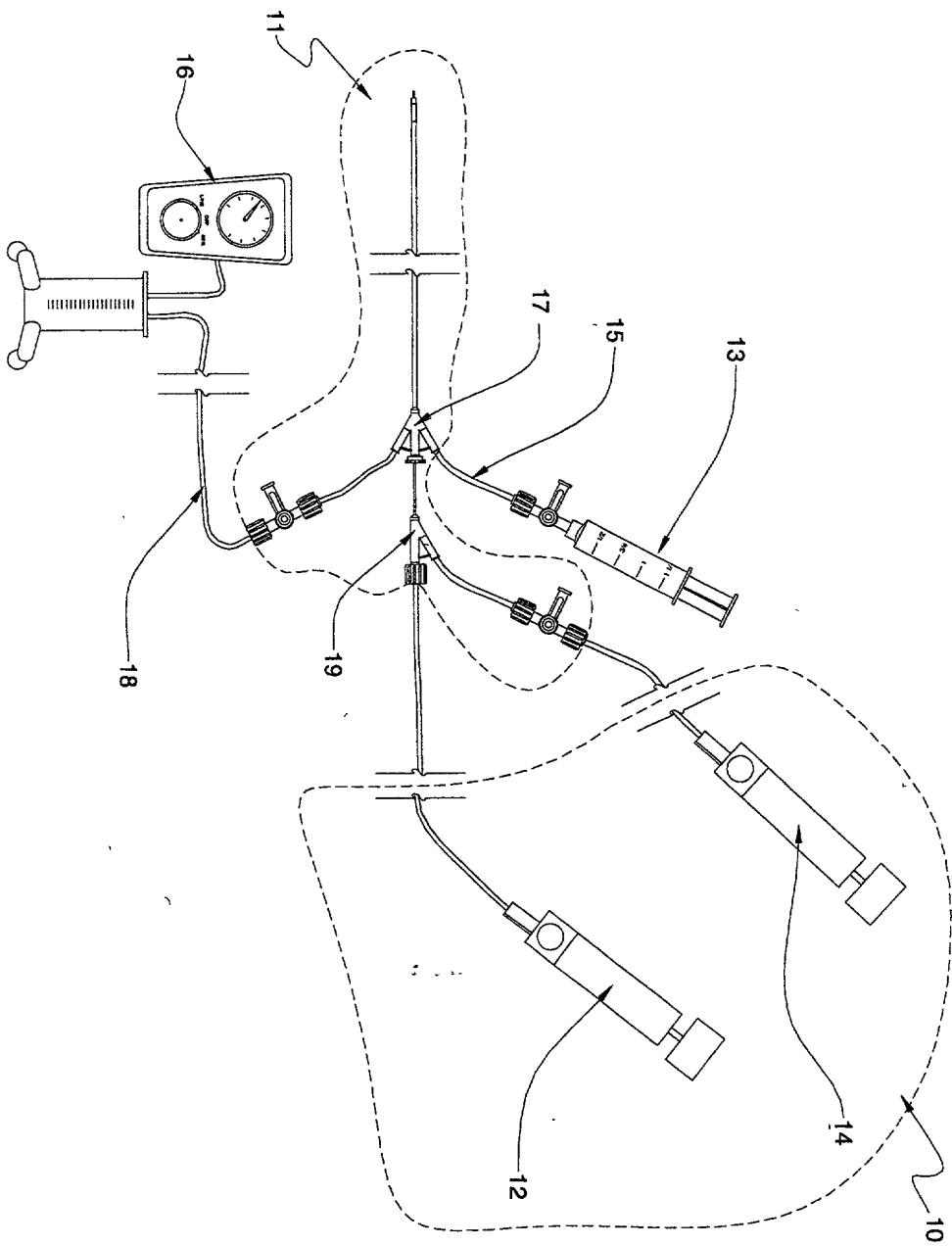


Figure 1

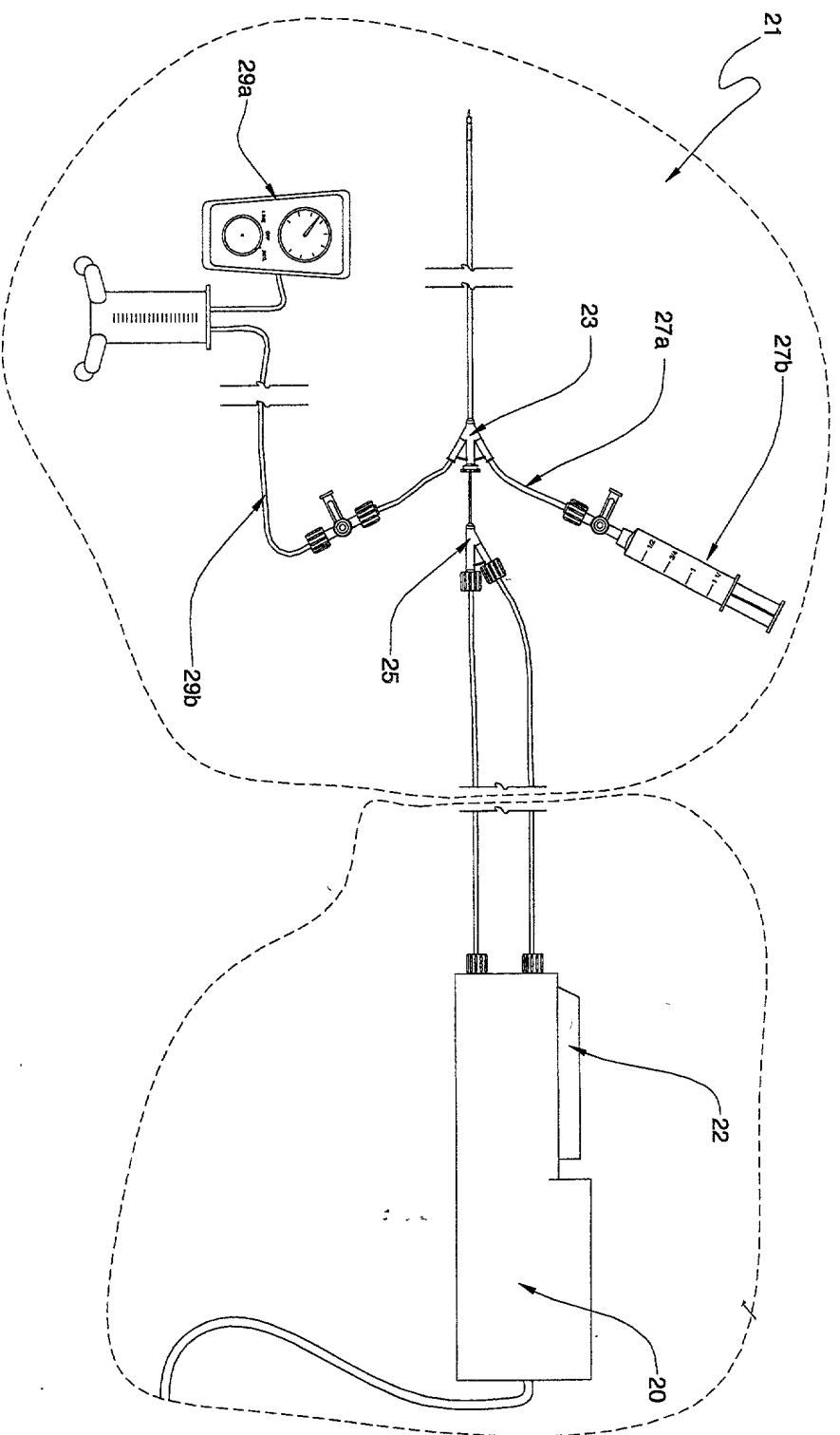


Figure 2A

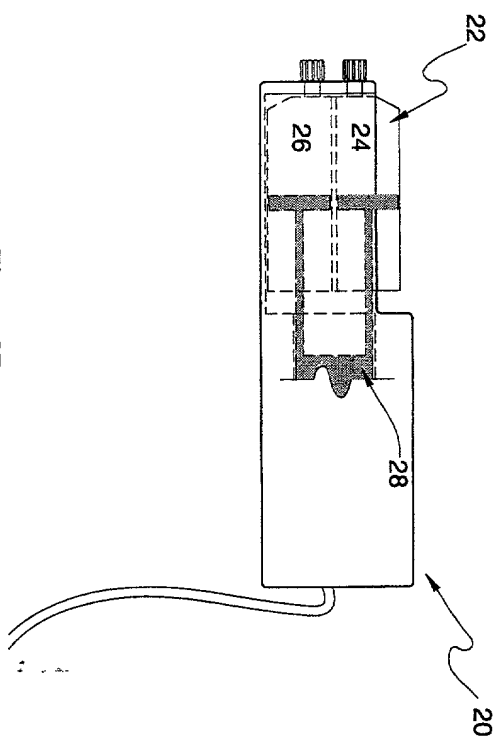


Figure 2B

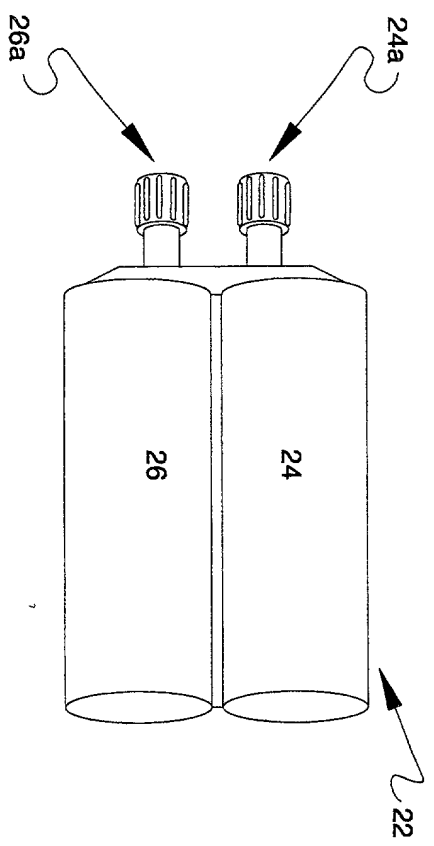


Figure 2C

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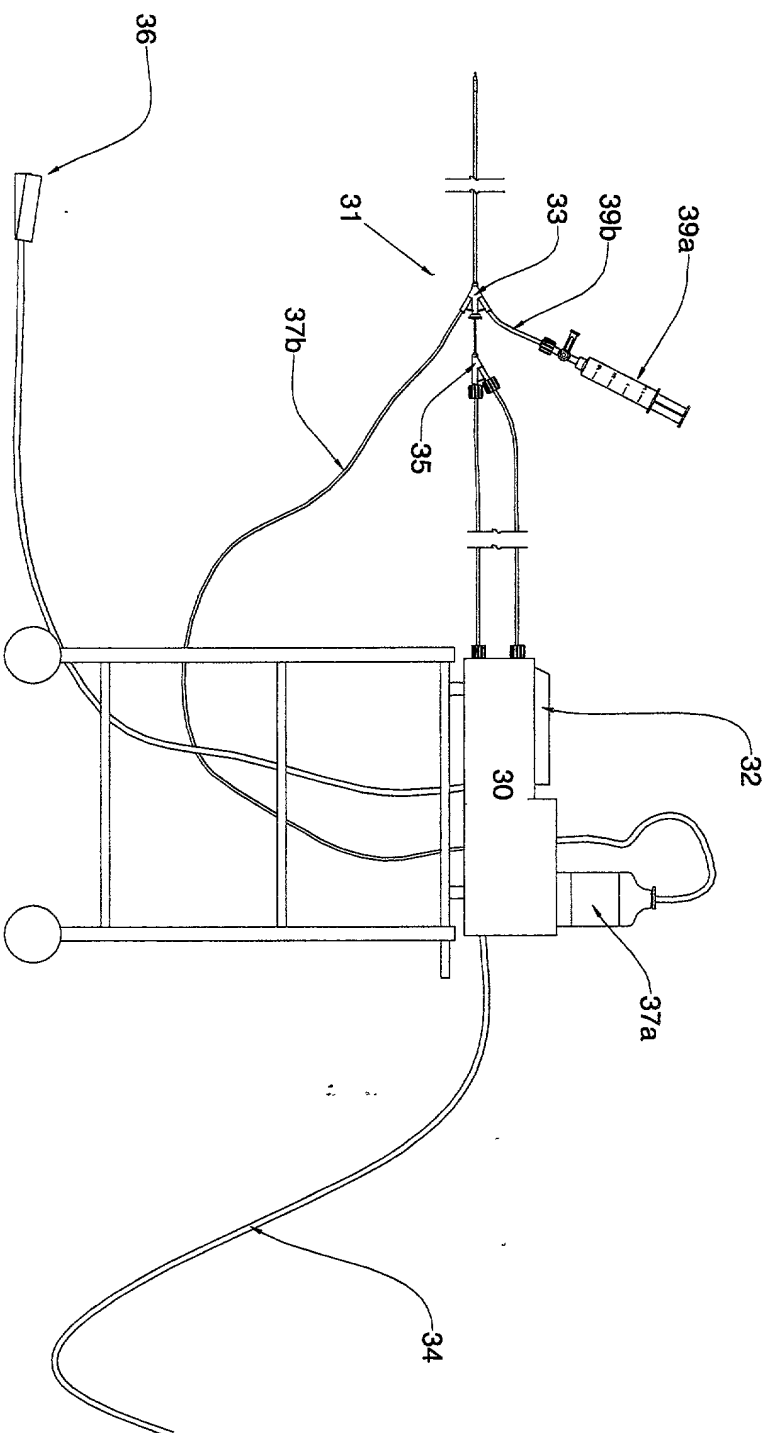


Figure 3

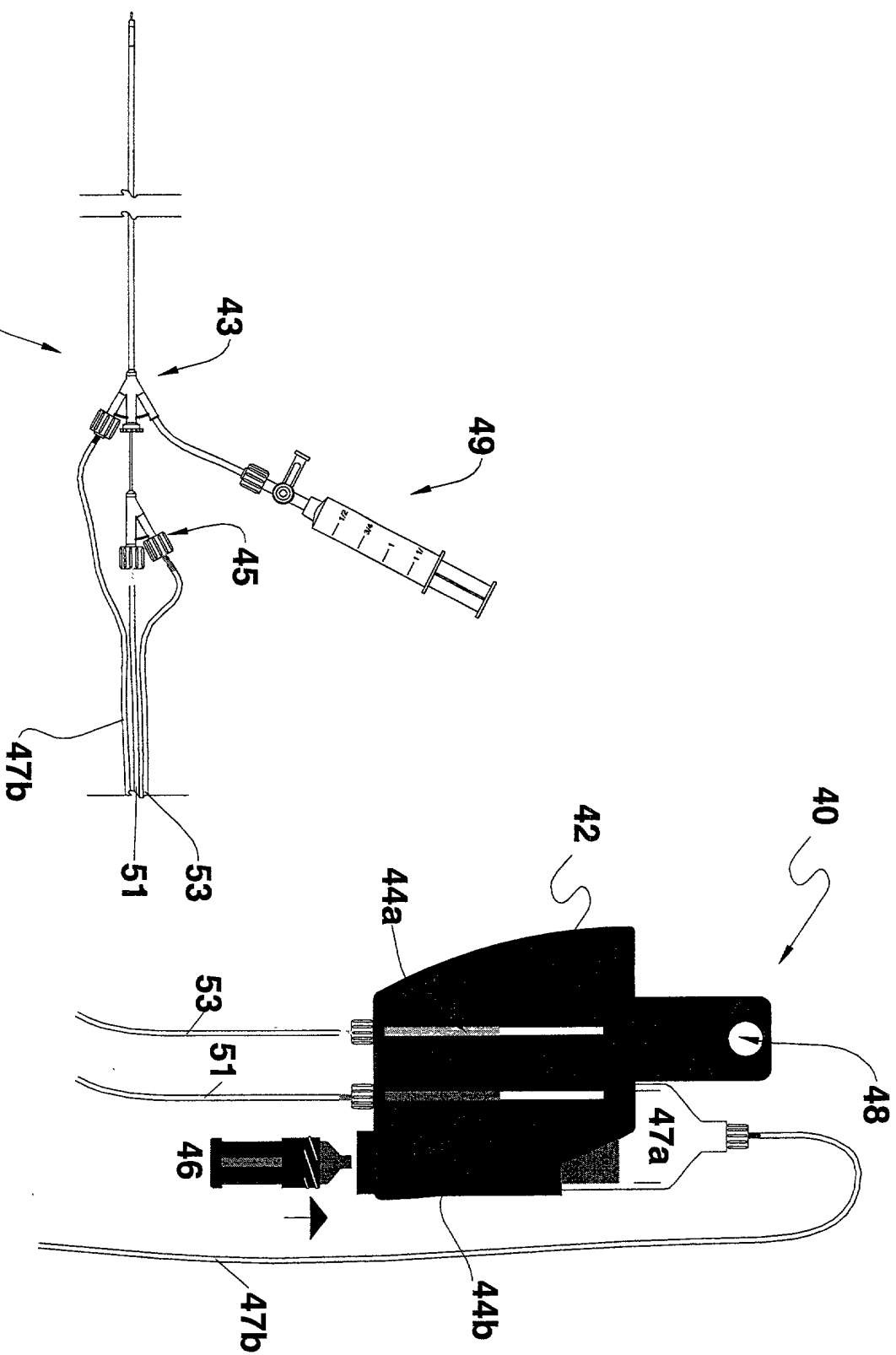


Figure 4

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)		Attorney Docket Number	CORA-011
		First Named Inventor	Brent R. Constantz
		COMPLETE IF KNOWN	
		Application Number	N/A
		Filing Date	Herewith
		Group Art Unit	N/A
Declaration Submitted with Initial Filing OR Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16(e)) required)		Examiner Name	N/A

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Fluid Delivery Systems for Delivering Fluids to Multi-Lumen Catheters

the specification of which is attached hereto.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined by 37 CFR 1.56.

Insofar as the subject matter of each of the claims of this application are not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designating at least one country other than the United States of America, listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) having a filing date before that of the application(s) of which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO

I hereby claim the benefit under 35 U.S.C. 119(c) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application(s) designating the United States of America, listed below.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

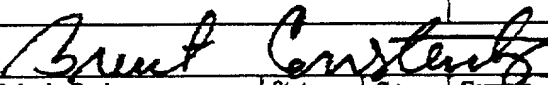
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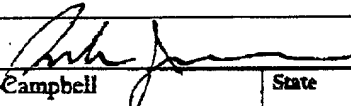
DIRECT ALL CORRESPONDENCE TO:					
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor:

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Inventor's Signature				Date	8/22/00		
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Peter K.				Johansson			
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**POWER OF ATTORNEY
BY ASSIGNEE**

Attorney Docket	CORA-011
First Named Inventor	Brent R. Constantz
Application Number	N/A
Filing Date	Herewith
Examiner Name (Group Art Unit)	N/A
Title: Fluid Delivery Systems for Delivering Fluids to Multi-Lumen Catheters	

Corazón Technologies, Inc., assignee of the above-identified application by assignment dated _____, hereby appoints:

BOZICEVIC, FIELD & FRANCIS LLP

Name	Registration No.	Name	Registration No.
Karl Bozicevic	28,807	Pamela J. Sherwood	36,677
Bret E. Field	37,620	Dianna L. DeVore	42,484
Carol L. Francis	36,513	Paula A. Borden	42,344
Alan W. Cannon	34,977	Nicole A. Verona	P-47,153

as its attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the Patent and Trademark Office connected therewith.

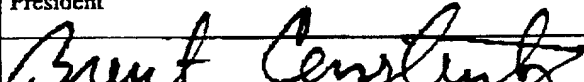
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Country	U.S.A.		
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SIGNATURE of Assignee of Record

In accordance with 37 CFR §3.73(b) I hereby certify that I am empowered to act on behalf of the Assignee of the above-identified patent application. The original assignment is enclosed herewith for recordation in the U.S. Patent Office.

I declare that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18, United States Code §1001 and that such willful false statements may jeopardize the validity of the above referenced application or any patent resulting from that application.

Name and Company	Brent R. Constantz, Corazón Technologies, Inc		
Title	President		
Signature		Date	8.22.00